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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/01/1995 09/01/1995 01/01/1995

TO THE DIRECTOR
OF THE PATENT AND
TRADEMARK OFFICE
WASHINGTON, D.C. 20231

09/01/1995

EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

02-18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

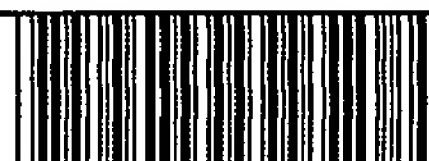
Office Action Summary

Application No.
09/005,105

Applicant(s)
Beatty et al.

Examiner
Eric Winakur

Group Art Unit
3736



☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) 1-8 and 12-28 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 9-11 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 - 17 and 23 - 25, drawn to a system for measuring electrophysiology data, classified in class 600, subclass 374.
 - II. Claims 18 - 22, drawn to a therapy catheter, classified in class 607, subclass 1.
 - III. Claims 26 - 28, drawn to a process for measuring electrophysiology data, classified in class 600, subclass 374.
2. The inventions are distinct, each from the other because of the following reasons: ~~Inventions~~
I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the system can be used with any therapy catheter. The subcombination has separate utility such as a therapy catheter for use outside of the heart.
3. Inventions I and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can perform another and materially different process, such as one which does not require the specific time or frequency domain analysis of the process claims.

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention: with regard to Group I - A) the system of claims 1 - 8 and 23, B) the system of claims 9 - 11, C) the system of claims 12 - 17, and D) the system of claim 24; with regard to Group II the following therapy catheters are claimed - A) with therapy electrodes (claim 18), B) with a drug delivery lumen (claim 19), C) with a microwave wave guide (claim 20), D) with a fiber optic cable (claim 21), and E) with an angioplasty balloon (claim 22); with regard to Group III - A) the process of claim 26, B) the process of claim 27, and C) the process of claim 28.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of

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an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Robert Beck on February 8, 1999 a provisional election was made without traverse to prosecute the invention of Group I, species B, claims 9 - 11. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1 - 8 and 12 - 28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The drawings are objected to because in Figures 1, 2, 8, and 16 the boxes should be labeled with the names of the elements in addition to the reference numbers. Correction is required.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 9 - 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claim 9, it appears that the phrase "a first catheter" (line 7) should read "said first catheter"; the phrase "at each of said set of passive electrodes" is unclear; it is unclear whether the phrase "a signal digitizer" (line 15) is meant to refer to the previously defined signal digitizer or if it meant to set forth a second digitizer; it is unclear what element the phrase "said signal digitizer" (line 21) is meant to refer to; the phrase "said wall distance measures" appears to be inconsistent with its antecedent; it is unclear whether Applicant intends to define one "converter means" having two functions or two different elements. With regard to claim 10, the term "an" should be inserted before "electric field" (line 6); it is unclear whether the "pulse generator" is meant to refer to the previously defined pulse generator or if it is meant to set forth a new element; it is unclear why Applicant includes a parenthetical phrase within the claim. With regard to claim 11, it is unclear what further structural limitation Applicant intends to set forth.

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 10 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 10 improperly incorporates a part of the body as part of the claimed subject matter by the phrase "said second catheter located in said heart chamber".

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13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 9 - 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Budd et al. in view of Ben-Haim. Budd et al. teach a system for mapping and representing the three-dimensional structure of the heart chamber that includes passive measurement and active interrogation electrodes, a signal generator, a signal digitizer, and a means for representing the endocardial wall. Budd et al. teach that their system is used for mapping the heart chamber, but do not teach or suggest measuring electrophysiologic signals and presenting representations of the electrophysiologic signals on the endocardial mapping output. Ben-Haim teaches an apparatus for treating cardiac arrhythmias that includes mapping the structure (with available imaging modalities) and electrical activity (such as with intracardiac electrograms) of a patient's heart and generating a detailed activation map from the data. Ben-Haim teaches that this representation of data allows mapping of electric pathways of the heart and identification of lesions to be ablated. Ben-Haim further teaches that location catheters are needed for proper three-dimensional correspondence of the various detected data. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Budd et al. to include elements for measuring electrophysiologic activity and displaying the measured data on the endocardial mapping output, and additionally, including location catheters in the system, as taught

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by Ben-Haim since this allows mapping of electric pathways through the heart, identification of lesions, and accurate alignment of the recorded data.

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Wittkamp teaches a catheter mapping system and method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Winakur whose telephone number is (703) 308 - 3940. The examiner can normally be reached on Monday - Thursday from 7:30 AM to 5:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cary O'Connor, can be reached on (703) 308- 2701. The fax phone number for this group is (703) 308 - 0758.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 - 0858.

Eric F. Winakur
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February 15, 1999